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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,650	11/28/2000	William D. Huse	06271.0024.DVUS01	5769

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02/11/2003

Patent Administrator
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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/11/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

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18

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Commissioner of Patents and Trademarks

--See attached--

Office Action Summary

Application No.

09/726,650

Applicant(s)

HUSE ET AL.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Iverson et al. (A').

The instant claims may be interpreted as being drawn to a combination of polypeptides comprising V_H and V_L , which combination exhibits catalytic activity, made by the recited method steps.

Iverson et al. teaches, e.g., as summarized in the Abstract and at column 10, lines 8-16, catalytic antibodies. At column 24, lines 17-35, F_{ab} molecules with catalytic activity are taught.

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Claims 22-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Schochetman et al. (B).

The instant claims may be interpreted as being drawn to a combination of polypeptides comprising V_H and V_L , which combination exhibits catalytic activity, made by the recited method steps. Claim 28 is drawn to combination which comprises an F_{ab} . It should be noted that an entire antibody may be understood as comprising an F_{ab} .

Schochetman et al. teaches, e.g., as summarized in the Abstract, catalytic antibodies.

Claims 22-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim et al. (C).

The instant claims may be interpreted as being drawn to a combination of polypeptides comprising V_H and V_L , which combination exhibits catalytic activity, made by the recited method steps. Claim 28 is drawn to combination which comprises an F_{ab} . It should be noted that an entire antibody may be understood as comprising an F_{ab} .

Kim et al. teaches, e.g., as summarized in the Abstract, catalytic antibodies.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention, for reasons of record set forth with respect to claims 16-21, now replaced by 22-29, in Paper No. 13, mailed 17 June 2002.

At page 5 of the amendment filed 25 November 2002, last paragraph, Applicants note that the previous Office Action characterized the claimed invention as "a product". This is correct. The claims under examination then were, and the instant claims are drawn to products, in the form of product-by-process. Such are still examined as products.

At page 6 generally, Applicants argue that "[t]he present invention is concerned with a synthetic method of producing a diverse genetic library which is representative of the immune repertoire of an animal." However, as noted above, the invention is actually drawn to products, recited as obtained from practice of the method in question. Applicants then argue that practice of the method in question is analogous to production of monoclonal antibodies in the art, in that detailed knowledge of the structure of the antibody would not have been required to produce the antibody. At page 7, Applicants argue that the method has been demonstrated to be successful, and that it eliminates the need for knowledge of the detailed structure of the V_H and V_L polypeptides. However, the present rejection is not for a lack of enabling disclosure, but rather for inadequate written description of the claimed invention, which is a product, and not a method. The claimed invention is drawn to a very broad genus, i.e., essentially any catalytic antibody. One cannot know the structure of such a catalytic antibody a priori, beyond the presence of certain conserved regions common to antibodies in general. Merely to set forth the function and the general class of a macromolecule is not sufficient to have conveyed to one of skill in the art that Applicants had a representative number of species from this genus in their possession at the time of filing.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to “[a] V_H and V_L polypeptide”. However, it is not clear if a single polypeptide comprising both a V_H and a V_L segment is encompassed, or a combination of two polypeptides as in an antibody or functional fragment thereof, such as an F_{ab}.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO

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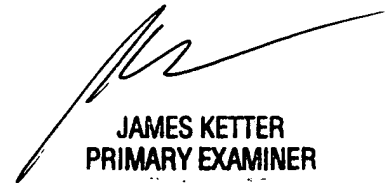
DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
February 5, 2003



**JAMES KETTER
PRIMARY EXAMINER**